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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Duncan J. Stewart

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EXAMINER

EPSS -SMITH, JANET L

ART UNIT

PAPER NUMBER

1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,743	Applicant(s) STEWART ET AL.	
	Examiner Janet L. Epps-Smith	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-88 is/are pending in the application.
- 4a) Of the above claim(s) 59,60,64 and 66-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-58,61-63,65 and 75-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 38-88 are pending. Claims 59-60, 64, and 66-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.
2. Claims 38-58, 61-63, 65 and 75-88 are pending for examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. The rejection of claims 39-44 and 63 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 38-58, 61-63, and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

7. Applicants have amended the instant claims and have added new claims 75-88. More specifically, Applicants have amended claims 38 and 55 to recite the phrase "encapsulated prepared cell suspension.." Additionally, Applicants recite a method of preparing a composition of prepared cells wherein the suspension includes an

encapsulation medium and “integrin binding partner bound or unbound to the prepared cells.” As support for these amendments Applicants cited the following passage found at page 19 of the specification, lines 8-12:

“[T]he encapsulated cells can be administered directly to the patient, e.g. by direct infusion of the encapsulated cell suspension, into the vasculature intravenously, or by injection directly into the target tissue, for example heart muscle, by percutaneous or surgical administration. They can also be administered to the lungs of a patient by processes of inhalation.”

Contrary to Applicant's assertions, the specification as filed does not provide support for wherein "a prepared cell suspension" is encapsulated. As set forth in claim 38 as originally filed, a cell is prepared by encapsulating a cell in a cell encapsulation medium. However, Applicant's specification as filed does not support wherein a “prepared cell suspension” is further encapsulated.

Claim Rejections - 35 USC § 102

8. The rejection of claims 38-39 and 41 under 35 U.S.C. 102(b) as being anticipated by Ramdi et al. (1993) is withdrawn in response to Applicant's amendment.

9. Claims 38-39, 41, 44-52, 55-58, 63, and 65 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schinstine et al. (US Patent No. 5,776,747).

10. Applicant's arguments filed 04/02/2009 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the teachings of Schinstine et al. is very different from that of the “instant invention which contemplates injection of single cells in suspension into the circulation or into tissues. Schinstine does not contemplate engraftment and incorporation of the prepared cell product into the host tissue. The hydrogel, matrix and/or integrin binding components

are designed to contain the cells and prevent their outgrowth (as pointed out by the Examiner). This is clearly substantively different from single cell capsules designed to allow cell outgrowth into the surrounding tissue to promote engraftment.”

11. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wherein the claims are drawn to single cells in suspension) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

12. Claims 38-58, 61-63, and 65 remain and claims 75-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinstine et al.

13. Applicant's arguments filed 04/02/2009 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that “it is unobvious from the cited art that including an integrin binding partner in an encapsulation medium to enhance cell anchorage of very large numbers of cells within large permanent or semi-permanent encapsulation structures, teaches one skilled in the art that the same component could be used in a suspension of individual cells to promote escape from the encapsulation medium.” In response to applicant's argument that the ordinary skilled artisan would not have appreciated that the same conditions cited in the art as useful for cell anchorage of a large number of cells would also be useful in a suspension of individual cells to promote escape from the encapsulation

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medium, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

14. Furthermore, contrary to Applicant's assertions, Schinstine et al. clearly teach the use of a derivatized matrix of agarose comprising an integrin binding partner laminin or fibronectin, and wherein the agarose is derivatized with an RGD containing sequence. This modification is described as having the ability to affect cell attachment to the matrix and to promote cell adhesion. According to the specification as filed the addition of fibrinogen to the encapsulation medium resulted also in the increased adherence of the cells. Moreover, encapsulation materials described by Schinstine et al. are also described as having the ability to support the viability of the encapsulated cells, see for example col. 18, lines 21-24, which recites wherein the modified encapsulation material is so designed to enhance cell survival. Therefore, contrary to Applicant's assertions, their observation regarding the increased viability of cells encapsulated in the presence of an integrin binding partner is not considered an unexpected property unique only to Applicant's disclosure.

15. Additionally, in Applicant's arguments traversing the rejection of the instant claims under 35 USC 103(a), Applicants made reference to the disclosure of Ramdi et al. at page 13, 2nd paragraph. It is noted that Ramdi et al. was not cited in the rejection of the instant claims under 35 USC 103(a).

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16. In regards to the newly added cells, 75-88, since the teachings of Schinstine et al. teach the encapsulation of cells, including individual cells (see example 9), and further teach that encapsulation in the presence of an integrin binding protein increases cell survival, Schinstine et al. as described in the prior Office Action and as discussed above is interpreted as reading on the newly added claims.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633